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an mail and		Application Number	10/805	,788	
TRANSMITTAL		Filing Date	Mar 22	, 2004	
FORM		First Named Inventor	Quay,	Steven C.	
		Art Unit	1614		
(to be used for all correspondence after initial t	iling)	Examiner Name			
Total Number of Pages in This Submission	189	Attorney Docket Number	03-04L	IS	
		LOSURES (Check all th	at apply	)	
Fee Transmittal Form		Drawing(s)		After A	llowance communication to (TC)
Fee Attached		Licensing-related Papers			Communication to Board of sand Interferences
Amendment / Reply		Petition		Appea	al Communication to TC al Notice, Brief, Reply Brief)
After Final		Petition to Convert to a Provisional Application		Propri	etary Information
Affidavits/declaration(s)		Power of Attorney, Revocation Change of Correspondence Ad	dress	Status	s Letter
Extension of Time Request		Terminal Disclaimer		X Other below	Enclosure(s) (please identify ):
Express Abandonment Request		Request for Refund		1) Form 144	9A (3 pgs)
X Information Disclosure Statement		CD, Number of CD(s)		· ·	nal Search Report ( <b>§</b> pgs)
Certified Copy of Priority Document(s)		Landscape Table on CD		3) Foreign R	eferences (181 pgs)
Reply to Missing Parts/ Incomplete Application	Rem	arks			
Reply to Missing Parts under 37 CFR 1.52 or 1.53					
SIGNA	TURE	OF APPLICANT, ATTORN	EY, OR	AGENT	
Firm Name Nesteph Pharmaceutica	I Compa	any Inc.			
Signature					
Printed name Peter J. Knudsen					
Date August 19, 2005			Re	g. No. 40682	
	EDTIC	CATE OF TRANSMISSION	/M A II II	NG	
I hereby certify that this correspondence is be sufficient postage as first class mail in an envedate shown below.	ing facsir	mile transmitted to the USPTO or	deposite	d with the Unite	
Signature And Cura	//	Trans			
Typed or printed name Jeffrey V. Granger				Date	August 19, 2005

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## THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Quay et al.

Group Art Unit: 1614

Serial No.: 10/805,788

Attorney Docket No.: 03-04US

Filed: 3/22/2004

Title: NASAL CALCITONIN

FORMULATIONS CONTAINING

CHLOROBUTANOL

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

## Dear Sir:

This Information Disclosure Statement is submitted:

X	under 37 CFR 1.97(b), or (Within three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)
	under 37 CFR 1.97(c) together with either a:  Statement under 37 CFR 1.97(e), or  a \$180.00 fee under 37 CFR 1.17(p), or  (After the CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
_	under 37 CFR 1.97(d) together with a:  Statement under 37 CFR 1.97(e), and a \$180.00 fee set forth in 37 CFR 1.17(p).  (Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

X Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

I hereby certify that this Correspondence is being deposited with the United States Postal service with sufficient postage for first class mail in an envelope address to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or the correspondence is being facsimile transmitted to the USPTO, on the date indicated below.

Date of Deposit: August 19, 2005

Typed Name: Jeffrey L. Granger

Signature:

Respectfully submitted,

Peter J. Knudsen

Attorney/Agent for Applicant(s)

Reg. No. 40682

Date: August 19, 2005

Telephone No.: 425-908-3643

PTO/SB/08a (08-03)

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rk Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. Complete if Known Substitute for form 1449A/PTO 10/805,788 Application Number INFORMATION DISCLOSURE 3/22/2004 Filing Date STATEMENT BY APPLICANT First Named Inventor Quay et al. **Art Unit** 1614 (Use as many sheets as necessary) **Examiner Name** Sheet of 3 Attorney Docket Number 03-04US 1

	U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Document Number  Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
		US-4,670,419	Issued 06-02-1987	Takeda Chemical Industries, Ltd.	*****		
		US-4,690,952	Issued 09-01-1987	Yamanouchi Pharmaceutical Co., Inc.			
··············	<u> </u>	US-4,788,221	Issued 11-29-1988	Yamanouchi Pharmaceutical Co., Ltd.			
·····		US-4,985,242	Issued 01-15-1991	Teljin Limited			
		US-4,988,512	Issued 09-18-1989	Sandoz Ltd.			
		US-5,026,825	Issued 06-25-1991	Rhone-Poulenc Rorer Pharmaceuticals, Inc.			
		US-5,059,587	Issued 10-22-1991	Toyo Jozo Company, Ltd.			
	}	US-5,091,365	Issued 02-25-1992	Hoechst Aktiengesellschaft			
		US-5,112,804	Issued 05-12-1992	Temple University of the Commonwealth System of Higher Education			
		US-5,124,315	Issued 06-23-1992	Phideatech S.R.L.			
	I	US-5,153,308	Issued 10-06-1992	Teijin Limited			
		US-5,179,079	Issued 01-12-1993	Novo Nordisk A/S			
		US-5,183,802	Issued 02-02-1993	ISF Societa per Azioni			
		US-5,200,393	Issued 04-06-1993	The Liposome Company, Inc.			
		US-5,204,108	Issued 04-20-1993	Danbiosyst UK Ltd.			
		US-5,211,950	Issued 05-18-1993	Teijin Limited			
		US-5,215,739	Issued 06-01-1993	Toko Yakuhin Kogyo Kabushiki Kaisha			
		US-5,281,580	Issued 01-25-1994	Toyo Jozo Company, Ltd.			
		US-5,321,008	Issued 06-14-1994	Amylin Pharmaceuticals, Inc.			
		US-5,428,006	Issued 06-27-1995	Bechgaard International Research and Development A/S			

	FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т6
		FR 2.205.308	05-31-1974	Farbwerke Hoechst AG		1
	1	EP 0 111 841 A1	06-27-1984	Syntex (U.S.A.) Inc.		
		EP 0 115 627 A1	08-15-1984	Armour Pharmaceutical Company		
		EP 0 183 527 B1	06-04-1986	Yamanouchi Pharmaceutical Co. Ltd.		
		EP 0 193 372 A2	09-03-1986	Teijin Limited		

Examiner	Date	
Signature	Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1Applicant's unique citation designation number (optional). 2See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6Applicant is to place a check mark here if English language Translation is attached.

Translation is attached.

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03-04US

Attorney Docket Number

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Sheet

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			U.S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No. 1	Document Number  Number - Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,428,706	Issued 6-27-1995	Coflexip	
		US-5,482,931	Issued 01-09-1996	Ferring AB	
		US-5,503,827	Issued 04-02-1996	Boehringer Mannheim GmbH	***************************************
		US-5,508,260	Issued 04-16-1996	Amylin Pharmaceuticals, Inc.	
		US-5,514,365	Issued 05-07-1996	Schiapparelli Salute S.P.A.	
		US-5,527,771	Issued 06-18-1996	Amylin Pharmaceuticals, Inc.	
		US-5,554,378	Issued 09-10-1996	Takeda Chemical Industries, Ltd.	
		US-5,565,423	Issued 10-15-1996	Hoechst Aktiengesellschaft	
		US-5,574,006	Issued 11-12-1996	Dott Research Laboratory	
		US-5,576,016	Issued 11-19-1996	Pharmos Corporation	
		US-5,578,324	Issued 11-26-1996	Teijin Limited	
		US-5,603,943	Issued 02-18-1997	Dott Research Laboratory	
		US-5,654,000	Issued 08-05-1997	Poli Industria Chimica S.p.Al	
		US-5,681,811	Issued 10-28-1997	Protein Delivery, Inc.	
		US-5,693,608	Issued 12-02-1997	Bechgaard International Research and Development A/S	
		US-5,719,122	Issued 02-17-1998	SmithKline Beecham Farmaceutici S.p.A.	
		US-5,725,852	Issued 03-10-1998	Takeda Chemical Industries, Ld.	
		US-5,725,871	Issued 03-10-1998	Danbiosyst UK Limited	
		US-5,733,569	Issued 03-31-1998	Novartis Corporation	

		FOREIG	N PATENT DOCL	IMENTS		
Examiner	<b></b>	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines,	
Initials*	Cite No.1	Country Code <sup>3</sup> - Number - Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	Т6
		GB 2 177 914 A	02-04-1987	Chugai Seiyaku Kabushiki Kaisha		
		EP 0 358 234 A2	03-14-1990	Rorer International (Overseas) Inc.		
		EP 0 371 010 A1	05-30-1990	Yamanouchi Pharmaceutical Co. Ltd.		
		EP 0 418 697 A1	03-27-1991	Esseit s.a.s. Laboratorio Chimico Farmaco Biologico Di A. Ievoli & C.		
***************************************		EP 0 471 618 A1	08-12-1991	Toyo Jozo Co., Ltd.		
		EP 0 489 217 A1	06-10-1992	DR. A Tosi Farmaceutici S.R.L.		

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3/22/2004

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Filing Date

Art Unit

First Named Inventor

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 3 Attorney Docket Number 03-04US

			U.S. PATENT	DOCUMENTS	
		Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
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		US-5,759,565	Issued 06-02-1998	Novartis Corporation	
		US-5,859,048	Issued 01-12-1999	Teikoku Hormone MFG. Co., Ltd.	
		US-5,948,749	Issued 09-07-1999	Fuji Yakuhin Company, Limited	
		US-6,078,338	Issued 07-11-2000	Therapicon S.R.L.	
	1	US-6,149,893	Issued 11-21-2000	Alfa Wasserman S.p.A.	
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		US-6,174,857 B1	Issued 01-16-2001	Novartis Corporation	
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		US-20020037836 A1	03-28-2002	Henriksen, Dennis Bang	
		US-20020068092 A1	06-06-2002	Bosch, H. William; et al.	
		US-20020076441 A1	06-20-2002	MacroMed, Inc.	
		US-20020107265 A1	08-08-2002	Chen, Feng-Jing; et al.	
	<u> </u>	US-20020110525 A1	08-15-2002	Adjei, Akwete L.; et al.	
		US-20020110527 A1	08-15-2002	Zhu, Yaping; et al.	
		US-20020110528 A1	08-15-2002	Zhu, Yaping; et al.	
		US-20020110528 A1	08-15-2002	Znu, raping; et al.	

	FOREIGN PATENT DOCUMENTS						
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		WO 99/16427 (Int. App. No. PCT/US98/20548)	04-08-1999	Emisphere Technologies, Inc.			
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Examiner	Date	
Signature	 Considered	

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